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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

7590 10/12/2006

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/402,564	<b>Applicant(s)</b> LOUVEL ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/15/06 has been entered.

### ***Claim Rejections - 35 USC § 112***

1. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. the claim recites "... The extruded filaments., wherein said tool is equipped with cutters in the form of blades having a first and a second face parallel with one another, the fist of which is inclined toward the second, thus forming a cutting edge, the second face being recessed so as to leave a strip of a width of less than 1mm which comprises the cutting edge whereby the shape of the particles obtained by chopping the extruded filaments is directly spheroidal without any additional spheroidal shaping step". The claim is not clear because, when a filament is chopped by blades the resulting shape is expected to be a discoid and not a spheroid, to get a spheroid, there should be an additional step to be obtained from a discoid.

Note that:

The definition of a discoid is:

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disc-shaped, flat, and circular.

[intramar.ugent.be/nemys/fungi/web/glossary.htm](http://intramar.ugent.be/nemys/fungi/web/glossary.htm)

The definition of a spheroid is:

a shape that is generated by rotating an ellipse around one of its axes; "it looked like a sphere but on closer examination I saw it was really a spheroid"

[wordnet.princeton.edu/perl/webwn](http://wordnet.princeton.edu/perl/webwn)

2. Claim 10 recites the limitation "due to which the particles obtained by the method including the maturing step introduce into the organism an increased quantity of active ....etc" in line 13. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. WO 96/14058 in view of Martin et al. US 5811186.

Oshlack et al (WO 96/14058) disclosed an apparatus (Fig 9/17), an extrusion system for making particles comprising extruder drive motor, controls cooling and temperature controls, feed hopper, a die, pelletizer which contains rotating cutter, rollers, fixed knife and the like (page 21, lines 29-30 bridging to page 22, lines 1-14).

Oshlack disclosed the method of manufacturing particulates (page 23, lines 10 and page 33, lines 15-28 to page 34, lines 1-5) and forming hard gelatin capsules formulation wherein the temperature employed is 83 degrees (page 23, lines 17, 105 degrees, page 24, lines 21-23); and wherein the extruded strands (filaments) or strands are congealed and cut into desired size (page 23, lines 29). Oshlack disclosed the use of the thermoplastic polymer like acrylic polymer, Eudragit (page 24, lines 19-22) or ethylcellulose (examples 1, 9, and 10) and a plasticizer like diethylphthalate (example 7). Oshlack also disclosed that the extruded multiparticulate system can be in the form of spheroids (page 17, line 29) and that the extruded multiparticulates can be any geometrical shape within a size range; e.g. beads, microspheres, seeds, pellets (page 18, lines 5-9).

Oshlack also disclosed the same step disclosed in instant claim 10 in the same order of steps a) to e) in the instant application. The steps included:

a) selecting a drug, hydrophobic material and binder with any further excipients.

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- b) blending.
- c) feeding the extruder with the blend.
- d) extruding the resultant mass.
- e) transport to pelletizer (chopping).

Oshlack is deficient in disclosing the maturing step.

Martin discloses melt-extruded thermoplastic filaments or fibers. A thermoplastic polymer used is selected from a group of polymers like polyurethanes, and acrylic polymers (col. 17, lines 26+). Martin teaches that surprisingly, heat aging (maturing) was found to improve the blend's flex-fatigue resistance (col. 19, lines 16-19).

Accordingly, it would have been obvious to one of ordinary skills in the art to prepare particulates of an active agent using melt extrusion technique as disclosed by Oshlack to provide a sustained release active substance (page 6 lines 1-5) and combine it with Martin's disclosure to age the blend and adjust the temperature and period of aging according to the active substance included in the blend, the motivation would be the disclosure of Martin that the heat aging was found to improve the blend's flex-fatigue resistance. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

#### ***Response to Arguments***

4. Applicant's arguments filed 2/15/06 have been fully considered but they are not persuasive. Applicant argues that:

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Instant claim 8 defines a device proper for obtaining such particles directly after the exit of the extrusion die without the use of a spheronization step, the said device being neither disclosed nor rendered obvious by the prior art.

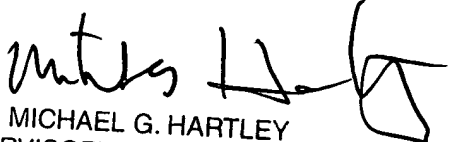
To respond: Oshlack disclosed the spheroidal particles in page 17, line 29 and did not disclose a separate step for spheronization.

Applicants contend that: Applicants did not contest disclosure by Oshlack of specific temperatures. However, Applicants had shown that the prior art reference does not disclose a maturing step outside the extruder.

This argument renders moot after adding martin to the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER